TECHNICAL NOTE

Balloon control of the saphenofemoral junction during foam sclerotherapy: Proposed innovation

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Venous obliteration using foam sclerosant is a relatively new procedure that holds great promise and may prove to be as effective as conventional surgical treatments in obliteration of the great saphenous vein. Foam sclerotherapy can have minor and major complications, most of which occur as a result of gas or sclerosant leakage into the systemic venous system. Conventionally, the saphenofemoral junction is occluded by digital pressure to prevent escape of sclerosant foam into the deep venous system. We propose balloon control of the saphenofemoral junction to prevent sclerosant leakage. This also promotes foam contact with the endothelium in a prolonged, controlled fashion. This method requires no anesthesia, is suitable for ambulatory care, and has been safe and successful in all five cases. Duplex examinations at 1 week and 3 months have shown complete obliteration of the great saphenous vein using this technique. (J Vasc Surg 2007;46: 145-7.)

Venous obliteration using sclerosant foam has become topical again. It holds great promise and may prove to be as effective as conventional surgical treatments.[1,2] Sclerosant foam therapy is a relatively simple procedure to perform and is usually accomplished without anesthesia.[1] The recent changes to surgical treatment of varicose veins have been accommodated by ready access to duplex-guided imaging, new foaming techniques, endovenous laser ablation, and radiofrequency obliteration.[3]

Foam sclerotherapy can have both minor and major complications. Minor complications can include ocular migraine, true migraine, chest tightness, visual disturbances, paresthesias, and bruising.[1,4] Reported major complication are deep venous thrombosis (DVT), femoral vein thrombosis, and stroke.[1,4,5] The United States Food and Drug Administration halted a clinical phase 2 trial of a commercial preparation of polidocanol microfoam in 2003 because of concerns relating to possible gas embolism. These trials were recommenced in July 2005. This report illustrates strong circumstantial evidence confirming the potential for embolic complication when this foam is used.[5]

The results of treatment are comparable with surgical intervention, with a small percentage of patients presenting complications, including DVT of the gastrocnemius and posterior tibial veins.[1] A case of femoral vein thrombosis was reported in a large multicenter study of sclerotherapy.[4]

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Competition of interest: none.
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0741-5214/$32.00

doi:10.1016/j.jvs.2007.03.020

Minor and serious complications can occur as a result of leakage of foam from the saphenofemoral junction (SFJ) or perforators.

Conventionally, the SFJ is occluded by digital pressure to prevent the escape of sclerosant foam into the deep venous system; however, this method does not reliably prevent leakage through the perforators or the SFJ. We propose a safety measure that is applied under ultrasound guidance and can minimize complications associated with foam sclerotherapy and help in the obliteration of the great saphenous vein (GSV).

PATIENTS AND METHOD

Five patients, all aged older than 65 years, underwent foam sclerotherapy in which local anaesthetic was used and the proposed innovation was incorporated. All patients underwent preoperative duplex imaging that showed isolated incompetent GSVs and patent deep systems.

Preoperatively, patient's veins were marked while they were in an upright position by using a duplex machine. Patients were then positioned supine on the operating table. An ultrasound probe was covered in a polyethylene sheath (civico). The limbs were prepared using antiseptic, and the patients were draped.

Perforators were located by duplex imaging (Titan, SonoSite, Bothell, Wash) and occluded by using a clip applicator. To access the perforators, a small incision was made under local anesthetic. The number of perforators clipped (Lega clip 20/20, Ethicon, Somerville, NJ) ranged from zero to four (Fig 1).

The GSV was accessed below the knee with an arterial needle under duplex control. A V18 Control wire (Boston Scientific, Natick, Mass) was introduced and followed to the groin. A Brite Tip long introducer and sheath (Cordis/

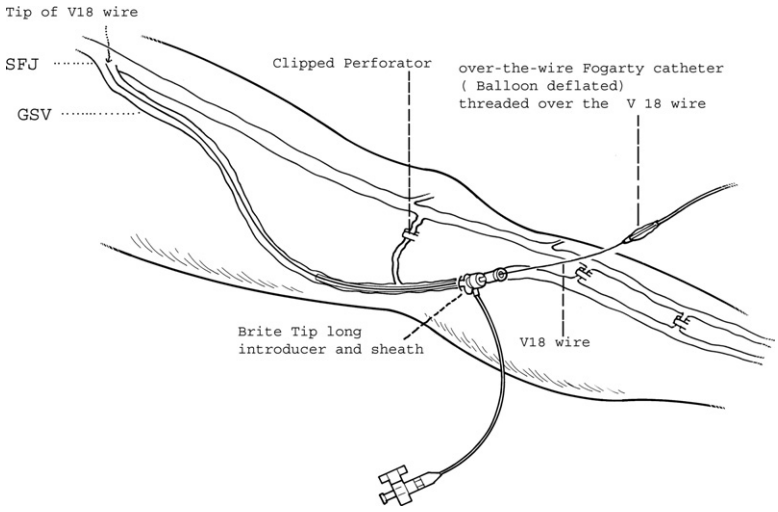

Fig 1. Drawing demonstrates the tip of V18 wire (Boston Scientific, Natick, Mass) at the saphenofemoral junction *(SFJ)*, the clipped perforators, long sheath, and introducer in the great saphenous vein *(GSV)*, and the over-the-wire Fogarty being threaded over the V18 wire.

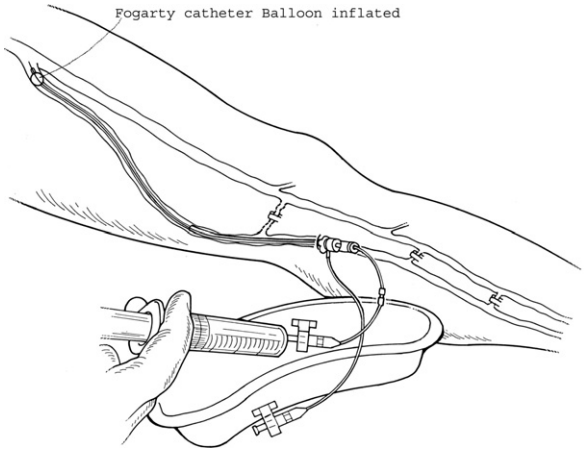

Fig 2. Drawing demonstrates the inflated balloon of the over-the-wire Fogarty catheter occluding the saphenofemoral junction.

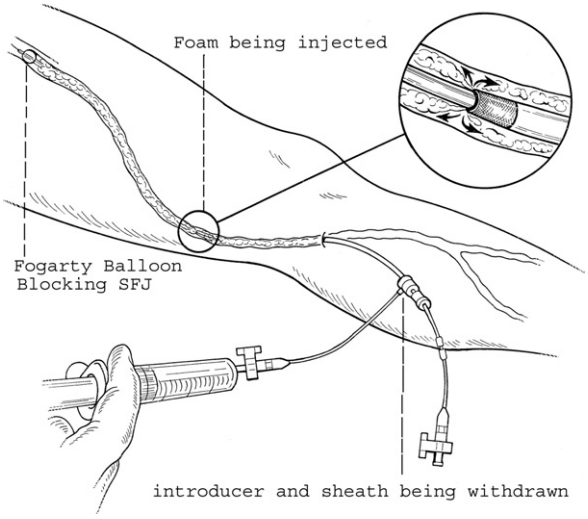

Fig 3. Drawing demonstrates the foam being injected *(inset)* from the side channel of long sheath, the Fogarty balloon occluding the saphenofemoral junction *(SFJ)*, and the sheath being gradually withdrawn to expose the distal end of great saphenous vein to foam.

Johnson & Johnson, Miami, Fla) was inserted over the wire using the Seldinger technique (Fig 1). The technique of using a long intravenous catheter has already been described by Milleret and Garandeau.[6] The position of the wire tip at the SFJ was confirmed by ultrasound imaging. The size of the vein at the junction was measured and a corresponding over-the-wire Fogarty catheter (LeMaitre Vascular, Burlington, Mass) was introduced coaxially.

Patients were then put in Trendelenburg position. The balloon of the over-the-wire Fogarty catheter was inflated 2 cm short of the SFJ, resulting in complete occlusion of the GSV (Fig 2).

Foam was prepared using 2 mL of sodium tetradecyl sulphate (3%) with 10 mL of air in two separate 5-mL syringes. The Tessari technique was used. The microbubbles in the foam provide an enormously increased area of surface contact.[7] Foam was injected (range, 5 to 10 mL) through the side arm of the long sheath. Injection of the foam was continued as the sheath was withdrawn to expose the distal end of the GSV to foam (Fig 3). The foam was left in contact with the GSV for 5 minutes. This was timed from the time of injection to the time when the balloon was deflated (Fig 4).

The V18 Control wire and long sheath were withdrawn first, and a small plaster was applied to the entry site. A thin line of sponge was placed along the line of the GSV, and compression with a Panelast Acryl (Vernon-Carus Ltd,

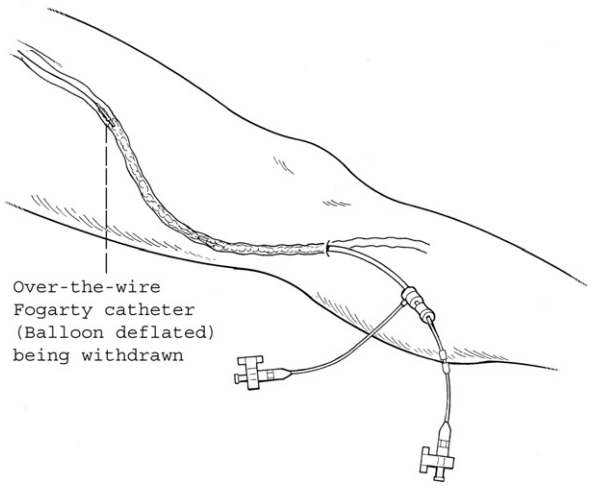

Fig 4. Drawing demonstrates the completed procedure but does not show the compression. Collapsed balloon of the-over-the wire Fogarty is being pulled out, and the sheath is almost out.

Lancashire, United Kingdom) adhesive bandage applied from foot to high thigh. The balloon was deflated after the compression was in place, and the leg was returned to the horizontal position.

The patients were then brought to the recovery room. No analgesics were prescribed. On discharge, the patients were encouraged to remain mobile and active. Compression dressings were left in place for 1 week and then replaced by a thromboembolic deterrent stocking.

RESULTS

All the patients were discharged from the hospital within 2 to 3 hours of the procedure. The compression bandage was removed at 1 week and replaced by an antiembolic stocking. The clinical examination at the 1-week visit revealed minor signs and symptoms relative to the procedure. No evidence of DVT was found on duplex examination. A duplex examination for all patients was repeated at 3 months, and the treated segments were completely obliterated in all five patients. There were no complications of either a major or minor nature.

DISCUSSION

Leak of sclerosant foam into the deep venous system from perforators and the SFJ junction has the potential to result in major and minor complications. Digital pressure is not reliable enough and results in leakage of sclerosant and gas into the deep venous system. Our use of an over-the-wire embolectomy catheter balloon eliminates the need for digital compression, and brings about uniform and prolonged contact of the foam with the endothelium. The completely blocked SFJ generates a static column of sclerosant foam, bringing about uniform contact with the venous endothelium.

As mentioned in "Methods," clipping the perforators before instillation should reduce the chances of foam escaping into the systemic venous circulation. Clipping of perforators also helps to further strengthen the static column of foam in the treated segment of vein.

CONCLUSION

We propose that this innovation of blocking the SFJ with an over-the-wire Fogarty balloon, along with clipping of perforators, can almost completely prevent leakage of gas and sclerosant into the deep venous system. This in turn, should minimize complications and improve the chances of success. The method is ideal for ambulatory care. This is a safe, simple, and cost-effective procedure that is well tolerated by patients.

REFERENCES

1. Bergan J, Pascarella L, Mekenas L. Venous disorders: treatment with sclerosant foam. J Cardiovasc Surg (Torino) 2006;47:9-18.
2. Bountouroglou DG, Azzam M, Kakkos SK, Pathmarajah M, Young P, Geroulakos G. Ultrasound-guided foam sclerotherapy combined with sapheno-femoral ligation compared to surgical treatment of varicose veins: early results of a randomised controlled trial. Eur J Vasc Endovasc Surg 2006;31:93-100.
3. Becker F. Current treatment of varicose veins. Curr Treat Options Cardiovasc Med 2006;8:97-103.
4. Guex JJ, Allaert FA, Gillet JL, Chleir F. Immediate and midterm complications of sclerotherapy: report of a prospective multicenter registry of 12,173 sclerotherapy sessions. Dermatol Surg 2005;31:123-8; discussion 128.
5. Forlee MV, Grouden M, Moore DJ, Shanik G. Stroke after varicose vein foam injection sclerotherapy. J Vasc Surg 2006;43:162-4.
6. Milleret R, Garandeau, C. Sclerose des grandes veines saphenes a la mousse delivree par catheter echo-guide sur veine vide: Alpha-Technique. Bilan des 1.000 premiers traitements. Phlebologie-Paris 2006;59:53-8.
7. Redondo P, Cabrera J. Microfoam sclerotherapy. Semin Cutan Med Surg 2005;24:175-83.

Submitted Oct 27, 2006; accepted Mar 11, 2007.